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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/444,790 02/19/90 BROCKHAUS

EXAMINER

ADAMS, D

ART UNIT	PAPER NUMBER
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GEORGE H BODLO
340 KINGSLAND STREET
MIDDELY NJ 07110

1811/0900

1816
DATE MAILED:

09/03/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☒ Responsive to communication filed on 5/30/96 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

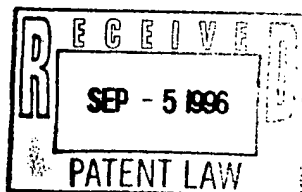
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-13 are pending in the application.
Of the above, claims 1-13 are withdrawn from consideration.
2. ☒ Claims 1-13 have been cancelled.
3. ☒ Claims 1-13 are allowed.
4. ☒ Claims 1-13 are rejected.
5. ☐ Claims are objected to.
6. ☐ Claims are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed , has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other
Copy Sent to
Department PLP



RESPONSE DUE: <u>December 3, 1996</u>
STATUTORY PERIOD EXPIRES: <u>March 3, 1997</u>

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Best Available Copy

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15. Please note the examiner and Art Unit handling this case has changed. Please direct all further communications to the below named examiner.

16. Claims 1-43 and 49 are canceled.

5 17. Applicant's election without traverse of in Paper No. 8 is acknowledged. Claim 55 is withdrawn from consideration as drawn to a non-elected invention.

18. Claim 48 is amended.

10 19. Applicant's request to withhold the filing of formal drawings until an indication of allowable subject matter is acknowledged.

20. 35 U.S.C. 101 reads as follows:

15 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

20 21. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

25 A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

30 22. Claims 48 and 50-53 are rejected under 35 U.S.C. 101 as being a substantial duplicate of claims 102-109 of co-pending application 08/095,640. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). CANCELED

35 23. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 45 should be amended to replace "contains" with -- has --. The sequence of Figure 1 appears to encode the entire 55 kDa protein, therefore an insoluble protein as claimed will have the amino acid sequence of Figure 1 and not contain it.

40 24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

25. Claim 54 is rejected under 35 U.S.C. 102(b) as being anticipated by Stauber et al. [JBC 263(35):19098-19104 (1988)]. Stauber et al. teach polyclonal antibodies which specifically bind TNF α , see page 19100, column 2. Applicant alleges that the protein is distinct from Stauber et al. and therefore an antibody that binds the Stauber et al. protein will not bind the protein of the instant invention. Applicant has not provided support for this allegation. Stauber et al. teach an antibody which will bind TNF α protein. The protein of claim 44 is a TNF α protein. The Stauber et al. Protein and the protein of the instant invention share the same properties, the ability to bind TNF α . Applicant bears the burden of providing evidence to demonstrate that the claimed antibody is different and unobvious over the antibodies of the cited prior art. See In re Marosi, 218 U.S.P.Q. 289, 292-293 (CAFC 1983).

26. Claim 54 is rejected under 35 U.S.C. 102(a) as being anticipated by Wallach et al. [EP 0 308 378 1989)]. Wallach et al. teach a partial sequence of the TNF receptor protein on page 3. This sequence is exactly the same as amino acids 12-27 disclosed in figure 1. Wallach et al. teach the production of antibodies at page 8. Applicant bears the burden of providing evidence to demonstrate that the claimed antibody is different and unobvious over the antibodies of the cited prior art. See In re Marosi, 218 U.S.P.Q. 289, 292-293 (CAFC 1983).

27. Claim 54 is rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. [U.S. Patent No. 5,395,760]. Smith et al. teach antibodies which specifically bind TNF-R, see column 26. Applicant bears the burden of providing evidence to demonstrate that the claimed antibody is different and unobvious over the antibodies of the cited prior art. See In re Marosi, 218 U.S.P.Q. 289, 292-293 (CAFC 1983).

28. Claims 44 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. [U.S. Patent No. 5,395,760]. Smith et al. teach a 55 kDa tumor necrosis factor receptor protein, DNA and expression vectors encoding the receptor.

29. Claim 46 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Wallach et al. [EP 0 308 378 1989)]. Wallach et al. teach a partial sequence of the TNF receptor protein on page 3. This sequence is exactly the same as amino acids 12-27 disclosed in figure 1. Therefore, Wallach et al. teach a soluble fragment of the of applicant's claimed protein.

30. Claim 45 is allowable.

31. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald E. Adams whose telephone number is (703) 308-0570. The examiner can normally be

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reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached at (703) 308-3973. The fax phone number for Group 1816 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

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August 27, 1996

Donald E. Adams

Donald E. Adams, Ph.D.

Primary Examiner

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Group 1800